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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,400	12/27/2001	Peng-Sheng Chen	18810-81904	9919

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EXAMINER

PARAS JR, PETER

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,400	CHEN, PENG-SHENG	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/27/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12/01.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-10 are pending. The preliminary amendment received on 12/27/01 has been entered.

Drawings

The drawings filed on 12/27/01 have been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to an animal model system for inducing a heart arrhythmia, the scope of which encompasses a human being. A human being is non-statutory subject matter. As such, the recitation of the limitation "non-human" would be remedial for the claims. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification has described a canine model system for artificially inducing heart arrhythmia. See throughout the specification. The specification however, has not described the other animals encompassed by the claims. There is no evidence on the record of a relationship between the structures of the animals embraced by the claims that would provide any reliable information about the structure of animals within the genus. There is no evidence on the record that the canine model had a known structural relationship to any other animals to be used as model systems of heart arrhythmia embraced by the claims; the specification discloses only a canine model and the art indicated that there is variation between the structures of the other animals to be used as model systems of heart arrhythmia. There is no evidence of record that would indicate that any of the other animals embraced by the claims, could even serve as model systems.

The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48

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USPQ2d 1641, 1646 (1998). However, it would appear that at the time the instant application was filed Applicants were not in possession of the animal model systems for heart arrhythmia encompassed by the claims, other than the canine model described above. The skilled artisan cannot envision the detailed chemical structure of the animal models encompassed by the instant claims, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of creating an animal model for heart arrhythmia. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

The skilled artisan would not recognize that applicant was in possession of the necessary common features or attributes possessed by the genus of animal model systems for heart arrhythmia embraced by the claims because a canine model is not representative of the claimed genus. Consequently, since Applicant was in possession of only the canine model and since the art recognized variation among the species of the genus of animals, the canine model was not representative of the claimed genus. Therefore, Applicant was not in possession of the genus of animal models for heart arrhythmia as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The neurotrophic vectors encompassed within the genus have not been disclosed. Based upon the prior art there is expected to be variation among the species neurotrophic vectors, because the structures of neurotrophic vectors would be expected to vary. The specification describes a method for practicing the claimed invention by administering nerve growth factor to stimulate myocardial hyperinnervation but does not describe methods for practicing the claimed invention by administering other neurotrophic vectors to stimulate myocardial hyperinnervation. There is no evidence on the record of a relationship between the structures of any neurotrophic vectors and nerve growth factor that would provide any reliable information about the structure of the other neurotrophic vectors within the genus. There is no evidence on the record that nerve growth factor had a known structural relationship to other neurotrophic vectors; the specification discloses only nerve growth factor for use in the claimed invention; the art indicated that there is variation between nerve growth factor and other neurotrophic vectors. There is no evidence of record that would indicate that any of the other neurotrophic vectors embraced by the claims would even be able to stimulate myocardial hyperinnervation. In view of the above considerations one of skill in the art

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would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus of neurotrophic vectors, because nerve growth factor is not representative of the claimed genus. Consequently, since Applicant was in possession of only methods requiring nerve growth factor and since the art recognized variation among neurotrophic vectors, nerve growth factor was not representative of the claimed genus. Therefore, Applicant was not in possession of the genus of neurotrophic vectors as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite as written. The claim embraces surgical and/or chemical blocking of the coronary artery. The term "and/or" renders the claim indefinite because it is not clear which step, either chemical or surgical or both, is used to block the coronary artery. Correction is required. Claims 2-10 depend from claim 1.

Claim 6 is unclear as written. The claim is directed to an ICD that further applies techniques to prevent the occurrence of further arrhythmias. The claim is unclear because neither the specification nor the art of record define techniques applied by an ICD. As such it is not known what is meant by techniques that are applied by an ICD. Clarification is required.

Claim 7 is unclear as written. The claim is directed to an ICD that further applies techniques to prevent the occurrence of ventricular arrhythmias. The claim is unclear because neither the specification nor the art of record define techniques applied by an ICD. As such it is not known what is meant by techniques that are applied by an ICD. Clarification is required.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

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**PETER PARAS
PATENT EXAMINER**

A handwritten signature in black ink, appearing to read "Pete Paras", written in a cursive style.